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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,293	11/13/2000	Jean-Louis Ruelle	BM45321	3367

25308 7590 05/07/2003

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EXAMINER

BASKAR, PADMAVATHI

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 05/07/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/700,293

Applicant(s)

RUELLE, JEAN-LOUIS

Examiner

Padmavathi v Baskar

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 60-67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 60-67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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Response to Amendment

1. The amendment filed on 1/29/03 has been entered into the record. Claims 60, 61 and 67 have been amended. Claims 60-67 are pending in the application.
2. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Rejections Withdrawn

3. In view of the amendment to claims, the examiner has withdrawn the rejection under 35 U.S.C. 112, second paragraph rejections.

Rejection Maintained

4. The examiner regrets the oversight made in referring the quotation 35 U.S.C. 102(e) in the previous Office action in paragraph # 7. However, the rejection is set forth below for applicant's convenience.
5. The rejection of claims 60-67 under 35 U.S.C. 102(e) as being anticipated by Peak et al 2001. U.S. Patent 6,197,312 is maintained as set forth in the previous Office action.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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The Claims are directed to an isolated polypeptide comprising a member selected from the group consisting of the (a) amino acid sequence matching SEQ.ID.NO: 2 or SEQ.ID.NO: 4 (b) an immunogenic fragment of at least 15 amino acids that matches an aligned contiguous segment of SEQ.ID.NO: 2 or 4. Further, the claims are also drawn to a fusion protein comprising said isolated polypeptide and an immunogenic composition comprising said polypeptide in a pharmaceutically acceptable carrier.

Peak et al disclose an isolated polypeptide SEQ.ID.NO: 9 comprising the amino acid sequence that contains 594 amino acids and matches 100% with SEQ.ID.NO: 2 in column 55-57 of U.S.Patent 6,197,312 (also see the attached sequence alignment). The disclosed polypeptide thus read on claim 1 (a). Further, the prior art also discloses immunogenic fragments containing at least 50 amino acids that include 15 or 20 amino acids of the claimed invention (see claim 5). The prior art discloses fusion proteins (see figure 1 and examples 2-4) and immunogenic compositions in the disclosed claims 7-10. The pharmaceutical composition as disclosed by Peak et al in claim 9 (see column 121) comprises two polypeptides in a pharmaceutically acceptable carrier and thus meet the limitation of the claimed immunogenic composition as recited in the present claim 67. The prior art anticipated the claimed invention.

Applicant's arguments filed on 1/29/03 have been fully considered but they are not deemed to be persuasive.

Applicant states that the prior art Peak et al is not a valid prior art reference under 35 U.S.C. 102(e) as per the American Inventors Protection Act of 1999. As stated above the examiner has rejected the claims under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)) as peak et al disclosed the claimed invention. The prior art 102 (e) date goes back to GB9726398 filed 12/12/97 because the issued U.S.Patent 6,197,312 is a PCT/AU98/01031 which claims priority to GB9726398 filed 12/12/97. Accordingly this is a valid prior art and filed before the filing date of the claimed invention (5/13/1998) by the applicant for patent. Therefore this rejection is maintained.

With respect to SEQ.ID.NO: 4, Applicant's attention is drawn to claim 60. Claim 60 is drawn to an isolated polypeptide comprising a member selected from the group consisting of (a) the amino acid sequence of SEQ.ID.NO: 2 or SEQ.ID.NO: 4. The claim does not require SEQ.ID.NO: 2 and SEQ.ID.NO: 4. Therefore, the examiner examined SEQ.ID.NO: 2.

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Status of Claims

6. No claims are allowed.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D.

5/5/03


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600